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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/049,366	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,24-27 and 31-35* is/are pending in the application.

4a) Of the above claim(s) *5,6,24-27,31-33 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-11 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Currently, claims 1 – 4, 7 – 11, and 34 are pending and under examination.

Claims 5, 6, 24 – 27, 31 – 33 and 35 are acknowledged as withdrawn as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 4, 7 – 11, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al. (US 5,939,331) in view of Killeen et al. (US 5,166,051).

Burd et al. teach a test device (biosensor) that is made of plural layers of porous material, said device having a labeling zone 26 (reagent holding part) which holds a labeled reagent for analyzing an analyte in a whole blood sample (liquid specimen

having cell components contained therein), said device analyzing target components in the sample by utilizing chromatography, said device further comprising:

a matrix 23 (carrier) carrying a cell-binding reagent having the ability of immobilizing cell components of said blood sample on at least a part of an area of said matrix, said area ranging from a sample (specimen) addition part to which the sample is added to a labeling zone 26 thereof; and

a nitrocellulose section 27 with capture zone 29 (reaction layer) chromatographically downstream of said matrix 23 on which a reaction between the analyte in the blood sample and the labeled reagent eluted from the labeling zone is carried out, permitting analysis of the analyte in the blood sample (see Figure 1; column 2, lines 8-62; column 5, lines 6-38; column 8, lines 14-67; column 9, lines 1-67; and column 10, lines 1-14).

However, Burd et al. fail to teach that the matrix includes a cell shrinkage reagent having the ability of making the cell components of said blood sample (liquid specimen) shrink, wherein the shrunk cell components are made smaller by said cell shrinkage reagent.

Killeen et al. teach a diagnostic test strip for chemically determining whole blood analytes comprising a support, a porous detection zone membrane, and an overlay membrane in overlying and continuous contact with the detection zone membrane. A sample of whole blood is applied to the overlay membrane, wherein the overlay membrane contains an effective amount of a crenating agent. The crenating agent functions to deplete the volume of fluid within the red blood cells, which shrinks and

rigidifies the cells, making them less flexible. The rigidified cells are less able to penetrate into the pores of the detection zone membrane, which allows for the passage of analyte that has been released from the solution of the whole red blood cells into the detection zone membrane (see Abstract; and column 5, lines 5-61).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Burd et al. a cell shrinking reagent within the sample addition matrix as taught by Killeen et al. because Killeen et al. teach the benefit of including a crenating (cell shrinking) reagent within a sample addition membrane, i.e. overlay membrane, of a test strip used in determining whole blood analytes because the crenating agent functions to deplete the volume of fluid within the red blood cells of a blood sample, which shrinks and rigidifies the cells, making them less flexible and less able to penetrate into the pores of the detection zone membrane, which allows for the passage of analyte that has been released from the solution of the whole red blood cells into the detection zone membrane.

With respect to Applicant's claim 2, Burd et al. teach that the sample is whole blood (see Abstract).

With respect to Applicant's claim 3, Killeen et al. teach that the liquid specimen, i.e. sample, can include bacteria (see column 6, lines 17-18).

With respect to Applicant's claim 4, Killeen et al. teach that the cell crenating (shrinkage) reagent is an inorganic salt (see column 5, lines 48-61).

With respect to Applicant's claims 7 and 9, Killeen et al. teach that the cell crenating reagent is dried naturally or air-dried with heat (see column 10, lines 34-39).

With respect to Applicant's claim 8, Burd et al. teach that the cell reagent applied to the sample matrix can be dried or lyophilized (freeze-dried) (see column 5, lines 6-12; and Example 1).

With respect to Applicant's claims 10-11, Burd et al. teach that the test device is a dry analytical element in the form of a one-step immunochromatographic test strip (see Abstract; Figure 1; column 9, lines 57-67; and column 10, lines 1-14).

With respect to Applicant's claim 34, Killeen et al. teach that the crenating reagent, preferably in the form of sodium chloride, should have a concentration from about 0.85 to about 35% (see column 5, lines 64-68; and column 6, lines 1-8).

Response to Arguments

Applicant's arguments filed April 28, 2008 have been fully considered but they are not persuasive. Applicant argues, see p9-14 and Exhibit, that the combination of Burd et al. in view of Killeen et al. would not result in Applicant's instant invention and would not function without being clogged with cell pieces or carry out an immune reaction without pre-processing. However, these arguments are not found persuasive.

First of all, Applicant appears to be arguing against the references individually and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,

208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Secondly, as discussed in the 103(a) rejection above, the Burd et al. reference teaches a test device (biosensor) that is made of plural layers of porous material, said device having a labeling zone 26 (reagent holding part) which holds a labeled reagent for analyzing an analyte in a whole blood sample (liquid specimen having cell components contained therein), said device analyzing target components in the sample by utilizing chromatography, said device further comprising:

a matrix 23 (carrier) carrying a cell-binding reagent having the ability of immobilizing cell components of said blood sample on at least a part of an area of said matrix, said area ranging from a sample (specimen) addition part to which the sample is added to a labeling zone 26 thereof; and

a nitrocellulose section 27 with capture zone 29 (reaction layer) chromatographically downstream of said matrix 23 on which a reaction between the analyte in the blood sample and the labeled reagent eluted from the labeling zone is carried out, permitting analysis of the analyte in the blood sample (see Figure 1; column 2, lines 8-62; column 5, lines 6-38; column 8, lines 14-67; column 9, lines 1-67; and column 10, lines 1-14).

However, Burd et al. fail to teach that the matrix includes a cell shrinkage reagent having the ability of making the cell components of said blood sample (liquid specimen) shrink, wherein the shrunk cell components are made smaller by said cell shrinkage reagent. Therefore, the secondary reference of Killeen et al. was combined with Burd et

al. in order to provide a teaching of and motivation for including a crenating agent within a diagnostic test strip, wherein the crenating agent functions to deplete the volume of fluid within the red blood cells, which shrinks and rigidifies the cells, making them less flexible. The rigidified cells are less able to penetrate into the pores of the detection zone membrane, which allows for the passage of analyte that has been released from the solution of the whole red blood cells into the detection zone membrane (see Abstract; and column 5, lines 5-61).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Burd et al. a cell shrinking reagent within the sample addition matrix as taught by Killeen et al. because Killeen et al. teach the benefit of including a crenating (cell shrinking) reagent within a sample addition membrane, i.e. overlay membrane, of a test strip used in determining whole blood analytes because the crenating agent functions to deplete the volume of fluid within the red blood cells of a blood sample, which shrinks and rigidifies the cells, making them less flexible and less able to penetrate into the pores of the detection zone membrane, which allows for the passage of analyte that has been released from the solution of the whole red blood cells into the detection zone membrane.

With regard to Applicant's arguments, Applicant merely presents the merits of their Application and an Exhibit of blood penetration according to their invention, but does not go into detail as to why or how the combination of Burd et al. in view of Killeen et al., which would include all of the necessary structural limitations and components of Applicant's claimed invention, would not function without being clogged with cell pieces.

The Burd et al. reference includes all of the structural requirements of Applicant's claimed invention, except for the inclusion of a cell shrinkage reagent (i.e. crenating agent) within the carrier component. Killeen et al. provide a teaching of and motivation for including a crenating reagent within a test strip device, wherein the crenating agent comprises the same compound as recited in Applicant's claimed invention, i.e. an inorganic salt. Therefore, because the combination of Burd et al. in view of Killeen et al. results in the biosensor device of Burd et al. including the crenating agent of Killeen et al., the combination of Burd et al. in view of Killeen et al. contains all of the structural limitations and components of Applicant's claimed invention and provides motivation thereof, and thus renders Applicant's claims unpatentable and obvious.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641